

**IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF PUERTO RICO**

Jeanette Perez Maceira, Jose Luis Mateo
Perez, and Lilliam M. Ortiz, individually
and on behalf of all others similarly situated,

Plaintiffs,

v.

Balchem Corp., Customed, Inc.,
Medtronic PR, Inc., Edward LifeSciences
Technology Sarl, Steri-Tech, Inc., and Mays
Chemical Company of Puerto Rico, Inc.,
Defendants.

Case No. 3:23-cv-1445

JURY TRIAL REQUESTED

CLASS ACTION COMPLAINT

NATURE OF THE ACTION

Ethylene oxide (“EtO”) is a known human carcinogen. As a gas, EtO is emitted into the air by institutions that sterilize medical instruments and preserve food, as well as by chemical plants producing items like antifreeze. Despite being labeled as cancer-causing by organizations like the EPA, National Toxicology Program, and the International Association of Research on Cancer, its discharge from medical sterilization facilities located on the island affects nearly 13% of neighborhoods in Puerto Rico.¹ Recent studies have shown a concerning trend: facilities releasing EtO are often located near areas predominantly inhabited by people of color, economically challenged individuals, and those who primarily speak languages other than English. These affected areas house vulnerable groups who disproportionately experience the adverse effects of a

¹<https://www.ucsusa.org/resources/puerto-rico#:~:text=The%20commonwealth%20of%20Puerto%20Rico,percent%20of%20its%20land%20area.>

problem they barely contribute to and often are not informed about the contaminants jeopardizing their health.

Chronic exposure to EtO has been linked to breast cancer, blood cancer, stomach cancer, leukemia, lymphoma, pancreatic cancer, brain cancer, reproductive issues, and miscarriages. In children, EtO can induce accelerated cell division, increasing DNA mutation risks. Short-term inhalation can cause symptoms like breathing difficulties, nausea, headaches, vomiting, tiredness, and neurological issues.

This action arises from injuries and damages sustained by Class Members as a proximate result of exposure to the toxic chemical EtO that was used on, stored on, and emitted from the premises owned and maintained by Defendants Customed, Inc., Medtronic PR, Inc., Edward LifeSciences Technology Sarl, and Steri-Tech, Inc. (hereinafter collectively referred to as “PR Sterilization Facilities”), distributed by Mays Chemical Company of Puerto Rico, Inc., and manufactured by Balchem Corp. by and through their managers and agents, and through their unsafe practices in sterilizing medical equipment, which released and emitted deadly EtO into the air of four Puerto Rican communities as part of that process.

INTRODUCTION

1. EtO was first listed in the *Fourth Annual Report on Carcinogens* in 1985 as *reasonably anticipated to be a human carcinogen* based on limited evidence of carcinogenicity from studies in humans and sufficient evidence of carcinogenicity from studies in experimental animals. The listing was revised to *known to be a human carcinogen* in the *Ninth Report on Carcinogens* in 2000.²

² *National Toxicology Program, Department of Health and Human Services*, Fifteenth Edition. “Ethylene oxide.” Page 1, <https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/ethyleneoxide.pdf>.

2. Despite these dangers, Defendants disregarded EtO's harmful properties and continued to release it into the surrounding communities.

3. For decades, Defendants have been emitting substantial quantities of EtO into the air supply of a sizeable population in Puerto Rico. As a result, those who live, work, pray, and attend school in the surrounding area of these facilities have unknowingly been inhaling EtO in the air they breathe on a routine basis.³

4. Defendants never informed the residents of these Puerto Rican communities or those who attend school, live, pray, or work nearby that it systematically emits EtO into the air, nor did Defendants warn them that they are routinely and continuously breathing in a known human carcinogen.

5. Through their industrial processes, Defendants emit EtO into the air, allowing it to be carried by the wind and natural air movement throughout the area surrounding the PR Sterilization Facilities. As such, residents' properties in the area have unknowingly been exposed to carcinogenic EtO for decades.

6. At all relevant times, the Defendants knew, or should have known, that EtO is dangerous, toxic, carcinogenic, mutagenic, and causes various illnesses. There is no safe level of EtO; its carcinogenic and DNA-damaging effects have been widely studied and known since the 1940s and definitively known to Defendants since at least 1984. Notwithstanding, Defendants chose to operate their business and emit EtO in a densely populated area full of children, houses, parks, schools, and businesses.

7. On February 7, 2023, the Union of Concerned Scientists published an intensive report ("USC report") on the exposure of EtO to communities in Puerto Rico. In the USC Report,

³ <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/salinas-puerto-rico-steri-tech-inc>

the Union of Concerned Scientists found that the maximum cancer risk levels from facility specific EtO emissions range from 800 to 6,000 cases per 1 million people, all of the EtO specific facilities are located within five miles of more than 413,000 Puerto Ricans (which constitute 13 percent of the population), and nearly 300 schools and childcare centers.

THE PARTIES

6. Plaintiff Jeanette Perez Maceira is a natural person and a citizen of the Commonwealth of Puerto Rico. She lives at Urb La Margarita Calle a F24 Salinas, PR 00751, within 400 feet of Steri-Tech and has lived in the residence since 1977. Ms. Perez Maceira was diagnosed with breast cancer in 2016 and had a mastectomy.

7. Plaintiff Jose Luis Mateo Perez is a natural person and a citizen of the Commonwealth of Puerto Rico. He is the son of Ms. Perez Maceira and also lives at Urb La Margarita Calle a F24 Salinas, PR 00751, within 400 feet of Steri-Tech and has lived in the residence since he was born in 1980. Mr. Mateo Perez developed asthma in 1984 when he was four years old.

8. Plaintiff Lilliam M. Ortiz is a natural person and a citizen of the State of Florida. She lived in the La Margarita Community from 1982-2007 less than a mile from the Steri-Tech facility and was diagnosed with thyroid cancer in 2022.

9. Defendants Customed, Inc., Medtronic PR, Inc. and Edward LifeSciences Technology Sarl and Steri-Tech, Inc., operate medical sterilization facilities in Puerto Rico using ethylene oxide ("EtO") manufactured by Balchem Corp. and distributed by Mays Chemical Company of Puerto Rico, Inc.

10. Balchem Corp. is a corporation organized and existing under the laws of its principal place of business located at 5 Paragon Drive, Montvale, New Jersey.

11. Defendant Customed, Inc is a domestic corporation organized and existing under the laws of Puerto Rico with its principal place of business located at Igualdad Street Final #7, Fajardo, Puerto Rico.

12. Defendant Medtronic Puerto Rico Operations, Co., also known as Medtronic PR, Inc. which operates a facility located at PR-149 KM 56.3 Villalba, Puerto Rico, is a corporation organized and existing under the laws of the Cayman Islands with its principal place of business located at Rd 909 Km 0.4 Mariana Humacao, PR, 00791, United States.

13. Edward LifeSciences Technology Sarl is a corporation organized and existing under the laws of Switzerland with its principal place of business located at Route de l'Etraz 70 Nyon, 1260, Switzerland.

14. Steri-Tech, Inc. is a corporation organized and existing under the laws of the Commonwealth of Puerto Rico with its principal place of business located at Parque Industrial, Salinas, Puerto Rico.

15. Mays Chemical Company of Puerto Rico, Inc., also doing business as Mays Ochoa, is a corporation organized and existing under the laws of the Commonwealth of Puerto Rico with its principal place of business located at Calle 2, Industrial Zone in the Barrio Palmas, Cataño, 00962, Puerto Rico. It also has a warehouse in Turabo Industrial Park and Gurabo, Puerto Rico.

JURISDICTION AND VENUE

16. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because (i) at least one member of the Class is a citizen of a different state than Defendants, (ii) the amount in controversy exceeds \$5,000,000, exclusive of interests and costs, and (iii) none of the exceptions under that subsection reasonably apply to this action.

17. This Court has personal jurisdiction over Defendants because they operate or previously operated industrial facilities in this District, currently conduct or previously conducted business throughout this District, and committed and continue to commit tortious acts within this District that are the subject of this suit.

18. Venue is proper pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims of Plaintiffs and the Class occurred in this District.

COMMON FACTUAL ALLEGATIONS

14. EtO is a flammable gas at room temperature that is produced in large volumes for industrial use. There are two primary known industrial uses for ethylene oxide: medical equipment sterilization and in other chemical production.

15. Ethylene oxide is highly explosive, toxic, carcinogenic, and DNA mutagenic.

16. EtO is highly reactive, readily taken up by the lungs, efficiently absorbed into the blood stream, and easily distributed throughout the human body. Its deleterious properties have been widely known for decades.

17. In a 1977 report, the National Institute of Occupational Safety and Health (“NIOSH”) concluded that occupational exposure to ethylene oxide may increase the frequency of genetic mutations in humans. The NIOSH report also raised a concern about the potential carcinogenicity of ethylene oxide.

18. In 1981, NIOSH released a subsequent report which recommended that EtO be regarded in the workplace as a potential occupational carcinogen. The NIOSH based its recommendation on new evidence of EtO’s carcinogenic, mutagenic, and reproductive hazards, including studies demonstrating that EtO induced cancer in experimental animals. Specifically, the studies showed an increase in instances of leukemia in line with the increase of EtO concentrations,

in addition to other adverse effects on reproductive health. An epidemiological investigation of Swedish workers exposed to EtO also revealed an increased risk of leukemia and other cancers.

19. In 1985, the U.S. Department of Health and Human Services published the Fourth Annual Report on Carcinogens and classified EtO as reasonably anticipated to be a human carcinogen.

20. In the early 1990s, the NIOSH published the largest and most informative epidemiological study of ethylene oxide. The study analyzed over 18,000 employees working with EtO at fourteen different industrial facilities sterilizing medical equipment and food spices. The study found sufficient evidence to support a causal link between exposure to ethylene oxide and increased mortality from lymphatic and hematopoietic cancers. Follow-up studies have additionally demonstrated an association between EtO exposure and breast cancer.

21. As a result of these findings, the World Health Organization (“WHO”) listed EtO as a Group 1 human carcinogen in 1994, the agency’s highest risk classification, finding ethylene oxide to be carcinogenic to humans. In 2000, the U.S. Department of Health and Human Services revised its classification for EtO to “known to be a human carcinogen.”

22. In 2016, the EPA’s Integrated Risk Information System reclassified EtO as carcinogenic to humans and increased the cancer potency of EtO by 30 times in adults and by 60 times in children.⁴

23. EPA’s Research and Development division revealed that half of the cancer risk from EtO occurs before the age of 16.⁵

⁴ Max Blau and Lylla Younes, *The Dirty Secret of America’s Clean Dishes*, ProPublica (Dec. 20, 2021) <https://www.propublica.org/article/the-dirty-secret-of-americas-clean-dishes>

⁵ Laredo EtO public meeting, Sept. 9, 2022 at 1:02:30, <https://www.youtube.com/watch?v=g8JeXQ3rvvg&t=6325s>

24. Exposure to EtO has been widely studied and its negative health effects are well documented. Presently, there is evidence linking exposure to increased risk of lymphohematopoietic cancer such as non-Hodgkin's lymphoma, multiple myeloma, and lymphocytic leukemia; breast cancer; tumors in the lungs, uterus, and the brain; and reproductive and developmental impairments including increased rate of miscarriages and infertility.

25. Commercial medical equipment sterilizers use the EtO sterilization process on over 20 billion health care products every year in the United States. The EtO sterilization process begins by placing medical equipment in a gas chamber. After air is pumped out of the chamber, EtO is injected and allowed to diffuse into the products for several hours. Once the medical equipment is sterilized, the ethylene oxide is pumped out of the chamber and the remaining EtO is allowed to slowly dissipate. Each time this sterilization cycle is run, EtO is emitted—whether through controlled or uncontrolled emissions known as “fugitive emissions”—into the air and inhaled by the surrounding community.

26. For chemical production, manufacturers cause EtO to undergo a chemical reaction to create new chemical compounds. Ethylene glycol is one of the most common chemicals synthesized from ethylene oxide and is often used in a wide range of products such as polyester fibers (for use in clothing, carpets, and upholstery), industrial coolants, antifreeze, and personal care products such as cosmetics, shampoos, body washes, and other skincare products.

27. Balchem Corp. is a global leader in the production and sale of performance gases, including EtO. EtO from Balchem Corp. is distributed in cylinders and drums globally as per the Balchem Corp. website. Page 5 of the August 24, 2022, data sheet available on the website (only in English) presents the following warning:

Statement of Hazards: DANGER! Extremely flammable liquid and gas under pressure. May form explosive mixtures with air. Highly Reactive. Harmful or fatal if inhaled and may cause delayed lung injury, respiratory system and nervous system damage. Inhalation

may cause dizziness or drowsiness. Liquid contact may cause frostbite. May cause allergic skin reaction. Harmful if swallowed. May cause adverse blood effects, liver and kidney damage based on animal data. Cancer and reproductive hazard.

HAZARD RATINGS: (0 = minimum; 4 = maximum)

HMIS Rating: Health = 3

Flammability = 4

Reactivity = 3

Personal Protection Code = X

28. Upon information and belief, Balchem Corp. provides training to the facility Defendants, namely Medtronic PR, Inc. (which has operated a facility at PR-149 KM 56.3 Villalba, Puerto since 1998) Customed, Inc. (which operates a facility at Igualdad Street, Fajardo, Puerto Rico since 2005), Steri-Tech, Inc. (which operates a facility at RD. 701 KM 0.7, Salinas, Puerto Rico since 1986) and Edwards LifeSciences Technology Sarl (which operates a facility located at 402 KM 1.4 Industrial Park, Anasco, Puerto Rico since 1989.)

29. According to the EPA, Balchem is the only EtO "technical registrant."⁶ A technical registrant is a company or individual that owns the source of the active ingredient in a pesticide product and has registered it with the EPA.⁷

30. A technical registrant is responsible for providing the data and information to support the safety and efficacy of the active ingredient, as well as complying with the EPA's regulations and requirements. A technical registrant typically has a significantly greater investment, as well as greater responsibilities and liabilities, than an end-use product registrant.

31. Upon information and belief, Balchem Corp. supplies EtO to its Puerto Rico distributor, Mays Ochoa, which distributes EtO to these facilities.

32. Through their industrial processes, these plants emit EtO into the air, poisoning the air in communities surrounding the facilities.

⁶ <https://www.epa.gov/system/files/documents/2023-04/eto-pid.pdf>

⁷ <https://www.epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

33. As such, local residents, students, and workers in the areas of these facilities have unknowingly been subjected to and breathed in EtO emissions for decades. All the while, PR Sterilization Facilities emitted EtO, Mays Ochoa distributed EtO, and Balchem Corp. manufactured EtO and knew, or should have known, that EtO is dangerous, toxic, carcinogenic, mutagenic, and the cause of various illnesses.

34. Named Plaintiffs and all Class Members suffered appreciable harm as a result of inhaling air poisoned with Defendants' dangerously high EtO emissions.

35. As a result of this harm, it is reasonably necessary for them to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of their EtO exposure. Monitoring procedures exist in the contemporary medical field that make possible the early detection of cancer, the disease progression of cancer, and the presence of biomarker abnormalities that indicate the development of cancer.

36. These diagnostic tests for the early detection of signs or symptoms of cancer are medically necessary to assure early diagnosis and effective treatment and to mitigate the risks of onset disease.

37. Having been harmed by regularly breathing in Defendants' elevated levels of EtO, Plaintiffs and Class Members seek as damages the costs of such diagnostic testing and medical monitoring, in order to detect the early onset of disease. This testing will, in turn, identify the need for treatment, management, and rehabilitation in the event cancer is detected and Plaintiffs and/or any Class Members are diagnosed.

FACTS SPECIFIC TO NAMED PLAINTIFFS

38. Plaintiff Jeanette Perez Maceira has been a resident of Salinas, Puerto Rico since 1989 within a five-mile radius of Steri-Tech at RD 701 KM 0.7 Salinas. Plaintiff suffered from breast cancer.

39. Plaintiff Jose Luis Mateo Perez has been a resident of Salinas, Puerto Rico since 1989 within a five-mile radius of Steri-Tech at RD 701 KM 0.7 Salinas. Plaintiff suffered from asthma.

40. Plaintiff Lilliam M. Ortiz—now a citizen of the State of Florida—lived in the La Margarita Community from 1982-2007, less than a mile from the Steri-Tech facility, and was diagnosed with thyroid cancer in 2022.

41. Named Plaintiffs, like many other Puerto Rican residents, unknowingly lived with and inhaled Defendants' carcinogenic EtO emissions for years.

42. Until recently, Named Plaintiffs had no reason to know the specific amount of EtO that Defendants were releasing, nor how dangerous these levels of EtO emissions were—including their association with elevated cancer risks—nor, that EtO was being emitted in their communities at all.

43. Plaintiffs reside or have resided in a radius of the facilities with EtO levels from approximately 2021 that, according to the U.S. EPA, corresponded with a cancer risk as high as 5000 cancer cases per million in Anasco, which is 500 times the national average cancer risk, 1000 cancer cases per million in Fajardo, which is 100 times the national average cancer risk, 6000 cancer cases per million in Salinas, which is 600 times the national average cancer risk, and 800 cancer cases per million in Anasco, which is 80 times the national average cancer risk.

44. These four facilities in Puerto Rico were all listed on a “red flag” list of 23 sites by the EPA—indicia of the far higher risk of EtO sterilization to Puerto Rican citizens than the American population at large.

45. Furthermore, these numbers do not reflect the cancer risks in these areas over time. According to the EPA, these risks are models based in large part on self-reported emissions data

that present a snapshot in time and may not fully capture fugitive emissions data and fail to show the risks over time and over the past decades.

46. The EPA estimates the percent of air toxins cancer risk attributable to EtO in these areas to be as high as 95.7%.⁸ In the cities where these four PR Sterilization Facilities are located, there are no other industries that use and emit EtO. Therefore, the only source of EtO and related cancer risk largely comes from the PR Sterilization Facilities.

47. High numbers of cancer cases are reported in areas surrounding these PR Sterilization Facilities. In 2019, Salinas reported 140 confirmed cases of cancers, among the highest incidence rates in Puerto Rico.⁹

CLASS ACTION ALLEGATIONS

66. **Class Definition:** Named Plaintiffs Jeanette Perez Maceira, Jose Luis Mateo Perez, and Lilliam M. Ortiz bring this action pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3) on behalf of themselves and a Class of similarly situated individuals, defined as follows:

All individuals who have resided, worked or attended school within a four-mile radius of Steri-Tech at Carretera 701 KM 0.7 Salinas Industrial Park; Customed Inc. at Carretera Igualdad Street #7, Fajardo; Edward Lifesciences at Parque Industrial Carr. PR-402 KM 1.4 N, Anasco; and Metronic PR Operation Co. at Carretera 151, PR-149 KM 56.3, Villalba, Puerto Rico beginning the date of initial emissions of Ethylene Oxide from each facility.

Excluded from the Class are: (1) any Judge or Magistrate presiding over this action and members of their families; (2) Defendants, Defendants' subsidiaries, parents, successors, predecessors, and any entity in which Defendants or their parents have a controlling interest, and its officers and directors; (3) persons who properly execute and file a timely request for exclusion from the Class; (4) persons whose claims in this matter have been finally adjudicated on the merits

⁸ <https://www.ucsusa.org/sites/default/files/2023-02/CommercialSterilizers-MON-FacilitySpreadsheet-2.6.23.xlsx>

⁹ <https://www.nbcnews.com/news/latino/contamination-salinas-puerto-rico-residents-demand-action-rcna68143>

or otherwise released; (5) Plaintiffs' counsel and Defendants' counsel; and (6) the legal representatives, successors, and assigns of any such excluded persons.

67. **Numerosity:** The exact number of Class members is unknown and not available to Plaintiffs at this time, but on information and belief, over 172,441 individuals fit within the definition of the Class. It is, therefore, clear that the members of the Class are so numerous that individual joinder is impracticable.

68. **Commonality and Predominance:** There are many questions of law and fact common to the claims of Plaintiffs and the putative Class and those questions predominate over any questions that may affect individual members of the Class. Common questions for the Class include, but are not necessarily limited to, the following:

- a. Whether Defendants' conduct was negligent;
- b. Whether Defendants' conduct was grossly negligent;
- c. Whether Defendants owed a duty of care to Class Members;
- d. Whether the duty of care owed to the Class included the duty to prevent their exposure to unsafe, unnecessary, and high levels of EtO emissions;
- e. Whether Defendants breached their duty to the Class by exposing them to high levels of EtO and, thus, increasing their risk of contracting illnesses;
- f. Whether Defendants underreported levels of EtO emissions;
- g. Whether Defendants failed to inspect, test, or warn the surrounding community about EtO's defects or hazards;
- h. Whether medical monitoring and early diagnostic detection is reasonably necessary to protect the Class; and

- i. Whether Named Plaintiffs and Class Members are entitled to relief, including through the establishment of a fund to provide for medical monitoring and diagnostic costs, damages are diagnosed injuries, wrongful death, and other legally available damage theories, including punitive damages.

69. **Typicality:** Plaintiffs' claims are typical of the claims of the other members of the Class in that Plaintiff and the members of the Class sustained damages arising out of Defendants' uniform wrongful conduct.

70. **Adequate Representation:** Plaintiffs will fairly and adequately represent and protect the interests of the Class and has retained counsel competent and experienced in complex litigation and class actions. Plaintiffs also have no interests antagonistic to those of the Class and Defendants have no defenses unique to Plaintiffs. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the members of the Class and have the financial resources to do so. Neither Plaintiffs nor their counsel has any interest adverse to the Class.

71. **Superiority:** Class proceedings are superior to all other available methods for the fair and efficient adjudication of this controversy, as joinder of all members of the Class is impracticable. Individual litigation would not be preferable to a class action because individual litigation would increase the delay and expense to all parties due to the complex legal and factual controversies presented in this Complaint. By contrast, a class action presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court. Economies of time, effort, and expense will be fostered, and uniformity of decisions will be ensured.

72. Plaintiffs reserve the right to revise the foregoing "Class Allegations" and "Class Definition" based on facts learned through additional investigation and in discovery.

COUNT I
Negligence

73. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

74. At all times relevant, Defendants owed a duty to Plaintiffs and the Class to exercise reasonable care in the operation of their facilities, including the emission of EtO.

75. Notwithstanding their duty, Defendants breached their duty in one or more of the following ways:

- a. Emitting dangerous volumes of EtO into the air from its facilities;
- b. Disregarding safe methods to adequately control EtO emissions from their facilities;
- c. Failing to warn or advise those who live, work, or attend school in the community that they were being exposed to EtO;
- d. Failing to adequately record test results of high levels of EtO;
- e. Ignoring test results of high levels of EtO;
- f. Underreporting EtO levels; and
- g. Subjecting those who live and work near their facilities to elevated cancer risks.

76. As a proximate result of Defendants' use and emission of EtO, Plaintiffs and the Class have breathed in air contaminated with elevated levels of EtO—amounts that are far higher and more hazardous than acceptable standards, including those set by the U.S. EPA.

77. This exposure makes it significantly more likely that Plaintiffs and Class Members will develop further injuries, including several types of cancer and other illnesses, including but not limited to, blood cancers, breast cancers, tumors, and reproductive issues. This makes periodic diagnostic medical examinations reasonably necessary.

78. Monitoring and diagnostic procedures exist that make early detection of these cancers possible and beneficial.

79. These monitoring and diagnostic procedures are different than those normally recommended in the absence of exposure to toxic gas such as EtO and are reasonably necessary due to Plaintiff's and Class Members' significant exposure to EtO.

80. As a result, Plaintiff and the Class should be awarded the costs of such a monitoring regime.

COUNT II
Gross Negligence: Willful and Wanton Misconduct

73. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

74. At all times relevant, Defendants owed a duty to Plaintiffs and the Class to exercise reasonable care in the operation of their facilities, including the emission of EtO.

75. At all times relevant, Defendants owed a duty to refrain from intentional, reckless, malicious, fraudulent, willful and wanton misconduct and/or conduct which exhibited an indifference and/or conscious disregard to the property, health, safety, and well-being of Plaintiffs and those living and working in the area surrounding the facilities. Defendants intentionally, recklessly, maliciously, and fraudulently caused unsafe Ethylene Oxide to emit from their facilities causing damage to Plaintiffs.

76. Defendants were motivated by financial profit to intentionally, recklessly, maliciously, fraudulently, willfully, and wantonly expose Plaintiffs to EtO by failing to take proper precautions to prevent the emission of unsafe levels of EtO from their facilities.

77. The conduct of each of the Defendants as set forth hereinabove showed intentional, reckless, malicious, and fraudulent misconduct. Accordingly, punitive damages should be

imposed against each Defendant to punish and deter each Defendant from repeating or continuing such unlawful conduct.

78. Notwithstanding their duty, Defendants breached their duty in one or more of the following ways:

- a. Emitting dangerous volumes of EtO into the air from its facilities;
- b. Disregarding safe methods to adequately control EtO emissions from their facilities;
- c. Failing to warn or advise those who live, work, or attend school in the community that they were being exposed to EtO;
- d. Failing to adequately record test results of high levels of EtO;
- e. Ignoring test results of high levels of EtO;
- f. Underreporting EtO levels; and
- g. Subjecting those who live and work near their facilities to elevated cancer risks.

79. As a proximate result of Defendants' use and emission of EtO, Plaintiff and the Class have breathed in air contaminated with elevated levels of EtO—amounts that are far higher and more hazardous than acceptable standards, including those set by the U.S. EPA.

80. This exposure makes it significantly more likely that Plaintiffs and Class Members will develop further injuries, including several types of cancer and other illnesses, including but not limited to, blood cancers, breast cancers, tumors, and reproductive issues. This makes periodic diagnostic medical examinations reasonably necessary.

81. Monitoring and diagnostic procedures exist that make early detection of these cancers possible and beneficial.

82. These monitoring and diagnostic procedures are different than those normally recommended in the absence of exposure to toxic gas such as EtO and are reasonably necessary due to Plaintiffs' and Class Members' significant exposure to EtO.

83. As a result, Plaintiffs and the Class should be awarded the costs of such a monitoring regime.

COUNT III

Public Nuisance pursuant to 32 L.P.R.A. §2761

84. Plaintiffs reallege and reaffirm each and every allegation set forth in all of the preceding paragraphs as if fully stated herein.

85. Puerto Rican law provides:

Anything which is injurious to health ... so as to interfere with the comfortable enjoyment of life or property, or that is a nuisance to the wellbeing of a neighborhood, or to a large number of persons ... constitutes a nuisance and the subject of an action. Such action may be brought by any person, public agency or municipality whose property is injuriously affected or whose personal enjoyment is lessened by the nuisance, and by the judgment the nuisance may be enjoined or abated, as well as damages recovered. 32 L.P.R.A. §2761.

86. Defendants' conduct has caused unreasonable and substantial interference with public health and comfortable enjoyment of life and property, such as by causing EtO to be emitted into the atmosphere.

87. Defendants' conduct was a substantial factor in causing Plaintiffs and other Class Members to have to pay medical costs.

88. By causing the emission of EtO into the atmosphere, Defendants have injuriously affected rights common to the general public, such as the rights of the people to public health, public safety, public peace, public comfort, and public convenience. The public nuisance caused by Defendants' conduct has caused substantial annoyance, inconvenience, and injury to the public.

89. The Defendants knew that their acts and/or omissions regarding the release of EtO would have a detrimental effect on the health of the Class.

90. Wherefore, Plaintiffs seek punitive and compensatory damages in excess of \$75,000 from all Defendants, jointly and severally.

COUNT IV
Strict Liability - Design Defect
31 L.P.R.A. § 10807

91. Plaintiffs restate, reallege, and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

92. Puerto Rican law provides:

People who sell in the flow of commerce a product that by its design or manufacture is unreasonably dangerous, are responsible for the damages that said product causes even if they do not incur fault or negligence. 31 L.P.R.A. § 10807, PRS ST T. 31 § 10807

93. Defendants' EtO mixtures and EtO-containing products as described herein constituted an unreasonably dangerous design of such products in that they contained EtO, a known toxic substance and carcinogen, at the time they left their control.

94. Defendants' EtO mixtures and EtO-containing products' toxicity, ability to bioaccumulate, inability to be contained, and environmental persistence rendered them defective and unreasonably dangerous at all times.

95. Defendants' ETO mixtures and ETO-containing products were unsafe as designed.

96. The risk of danger inherent in the design of the Defendants' ETO mixtures and ETO-containing products drastically outweighed any perceived benefits of the design of such products when such products were put to reasonably foreseeable uses.

97. Alternatively, Defendants knew their ETO mixtures and ETO-containing products were unsafe to an extent beyond that which would be contemplated by an ordinary person.

98. Practical and feasible alternative designs for Defendants' ETO mixtures and ETO containing products capable of reducing Class Members' injuries, damages, and financial losses were commercially available, including mineral oils, silicone fluids, vegetable oils, and nonfluid insulating chemicals, as well as alternative chemical formulations and/or additional chemical processing measures.

99. The ETO mixtures and ETO-containing products reached the Class Members' lands without any substantial change in condition from when they left the control of the Defendants.

100. The Defendants' unreasonably dangerous ETO formulas and ETO-containing products caused the permanent presence of ETO in Class Members and injury to the public interest, including threats to the physical and economic health and well-being of the Class Members.

101. Class Members have suffered, are suffering, and will continue to suffer into the indeterminable future medical costs as a result of Defendants' unreasonably dangerous ETO formulas and ETO-containing products and the presence of ETOs within Class Members.

102. The Defendants are strictly liable for all damages arising out of their defectively designed ETO formulas, mixtures, and ETO-containing products.

COUNT V
Strict Liability - Failure to Warn and Instruct
31 L.P.R.A. § 10806

103. Plaintiffs restate, reallege, and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

104. Puerto Rican law provides;

They are liable for the resulting damages, even if they are not at fault or negligent, except when the cause of the damage results from force majeure:

(d) the owners or possessors of property that constitutes a nuisance, as defined by law, for damages resulting from such condition; or for the storage of substances that threaten the safety of others; 31 L.P.R.A. § 10806, PRS ST T. 31 § 10806

105. Defendants' EtO and EtO-containing products were not reasonably safe at the time they left their control because they lacked adequate warnings and/or instructions concerning the dangers and hazards associated with EtO.

106. At the time the Defendants manufactured, distributed, marketed, promoted, and sold EtO and EtO-containing products, they knew their products were not safe and were likely if not certain to cause toxic EtO contamination of lands in Class Members.

107. Despite the Defendants' knowledge, they failed to provide adequate warnings and/or instructions that their EtO and EtO-containing products were toxic, carcinogenic, and would injure the Class Members' health and livelihood.

108. Defendants could have warned of and instructed about these dangers but failed to do so and intentionally concealed information in order to maximize profits for decades.

109. Defendants continued to conceal the dangers of ETOs after they manufactured, distributed, marketed, promoted, and sold ETOs and ETO-containing products.

110. The Class Members have suffered, are suffering, and will continue to suffer into the indeterminable future injuries as a result of medical needs attributable to the Defendants' conduct.

111. Defendants are strictly liable for all damages to the Class arising out of their failure to provide adequate warnings and instructions regarding their unreasonably dangerous ETOs and ETO-containing products.

COUNT VI

Negligent Design Defect

112. Plaintiffs restate, reallege, and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

113. The Defendants owed a duty of reasonable care to protect Class Members against the unreasonable health and safety risks resulting from the production, use, and disposal of EtO and EtO-containing products at their respective plants.

114. The Defendants failed to exercise ordinary care because a reasonably careful company—that knew of EtO’s toxicity, carcinogenicity, danger to humans, and destruction of the lands—would not manufacture, distribute, use, and dispose of those products; would warn of their toxic and environmentally hazardous properties; or would take steps to enhance the safety and/or reduce the toxicity and environmental persistence of the products.

115. The Defendants failed to exercise ordinary care because reasonably careful companies that knew that EtO could not be contained during normal production, distribution, use, and disposal efforts would not continue to manufacture, distribute, use, and attempt to dispose of EtO in a way that allowed the discharge of EtO into and onto Class Members lands.

116. The Defendants failed to exercise ordinary care because reasonably careful companies would not continue to manufacture, distribute, use, and dispose of EtO in mass quantities and to the extent and in the applications that Defendants manufactured and attempted to dispose of them.

117. Defendants’ EtO and EtO-containing products in Class Members caused and continue to cause injury and damage to the health and well-being of Class Members.

118. Class Members have suffered, are suffering, and will continue to suffer into the indeterminable future injuries as a result of Defendants’ failure to warn and instruct.

COUNT VII
Gross Negligent Design Defect

119. Plaintiffs reallege and reaffirm each and every allegation set forth in all the preceding paragraphs as if fully stated herein.

120. Defendants knew or should have known of the effects inherently caused by the normal use and operation of their EtO facilities and products, including the likelihood and likely severity of injury to those who live and work in the communities adjacent to facilities which emit EtO.

121. Defendants, collectively and individually, owed a duty to those who live and work in the areas surrounding the EtO facilities to exercise reasonable care in emissions of EtO from entering the area surrounding these facilities and prevent reasonably foreseeable harm that could have resulted therefrom.

122. Defendants knew or should have known that their actions might cause harm and consciously disregarded the foreseeable harm that could have resulted therefrom,

123. Wherefore, Plaintiffs seek punitive and compensatory damages in excess of \$75,000 from all Defendants, jointly and severally.

COUNT VIII
Private Nuisance pursuant to 32 L.P.R.A. §2761

124. Plaintiffs reallege and reaffirm each and every allegation set forth in all the preceding paragraphs as if fully stated herein.

125. Puerto Rican law provides:

Anything which is injurious to health ... so as to interfere with the comfortable enjoyment of life or property ... constitute a nuisance and the subject of an action. Such action may be brought by any person, public agency or municipality whose property is injuriously affected or whose personal enjoyment is lessened by the nuisance, and by the judgment the nuisance may be enjoined or abated, as well as damages recovered. 32 L.P.R.A. §2761.

126. Defendants' conduct has caused unreasonable and substantial interference with the Class Members' life and comfortable enjoyment of their life and property, causing substantial health impacts to the class, costs which have been unreasonably borne by the Class Members who suffered, and continue to suffer, losses by having to pay the cost to abate these risks to their health.

127. Defendants' conduct was a substantial factor in causing Plaintiffs to have to pay these costs and damage.

128. Wherefore, Plaintiffs seek punitive and compensatory damages in excess of \$75,000 from all Defendants, jointly and severally.

COUNT IX
Restitution – Unjust Enrichment

129. Plaintiffs reallege and reaffirm each and every allegation set forth in all the preceding paragraphs as if fully stated herein.

130. Defendants have avoided liability for these costs.

131. In equity and fairness, it is the Defendants, not the Class Members, who should bear the costs of healthcare for the Class Members. As a result, the Defendants have been unjustly enriched to the extent that the Class Members have had to pay these costs.

132. As a result of the Defendants' acts and omissions specified herein, the Plaintiffs were forced to expend far more in actual healthcare costs to identify and remedy their medical needs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the Class, requests that the Court enter judgment in their favor and against Defendants as follows:

- a. An Order certifying the Class as defined herein and appointing Named Plaintiffs and their Counsel as representatives of the Class;
- b. An award of damages, including nominal and compensatory damages, as allowed by law and in an amount to be determined;
- c. An Order creating a sufficient fund for a comprehensive medical monitoring program in an amount determined to be just and reasonable;
- d. An award of punitive damages as allowed by law and in an amount to be determined;
- e. An award of attorneys' fees, costs and litigation expenses;
- f. An award of prejudgment interest on all amounts awarded;
- g. An Order for injunctive and declaratory relief; and
- h. Such other and further relief as this Court may deem just and proper.

JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Respectfully submitted,
August 29, 2023

/s/ Douglas Sanders
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